

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

54-05

8/29/05

POLICY ON USE OF RESULTS FROM THIRD PARTY LABORATORIES

NOTE: This notice reissues the contents of FSIS Notice 52-03 in its entirety.

I. PURPOSE

FSIS is periodically presented with positive results from a laboratory analysis conducted by a third party laboratory that indicate an adulterant is present in FSIS inspected and passed product. A third party laboratory is one not owned by, nor under contract with, the establishment providing the sample. Under very limited circumstances, FSIS may rely on a third party laboratory's positive result to take action on the product (e.g., request a recall or take regulatory action). This notice describes the circumstances in which FSIS considers it appropriate to rely on results from a third party laboratory.

II. POLICY ON THIRD PARTY LABORATORY RESULTS

A. In deciding whether to rely on third party laboratory results, FSIS will consider the following questions (also see attached flowchart):

1. Were the procedures used to collect, handle, and transport the sample equivalent to FSIS procedures? FSIS will request documentation of the procedures used and will assess whether the integrity of the sample or specimen could have been compromised during collection or transportation.

2. Was the sample or specimen handled using a documented chain of custody establishing that the integrity of the sample or specimen was not compromised during transport from the point of collection to the laboratory or within the laboratory? FSIS will assess the documentation of the chain of custody to determine whether the people who handled the sample kept it intact and properly maintained throughout the process.

DISTRIBUTION: Inspection
Offices; T/A Inspectors; Plant Mgt;
T/A Plant Mgt; TRA; ABB; TSC;
Import offices

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3. Was there assurance that the results obtained by the third party laboratory are reliable and accurate for the analysis in question? FSIS will assess the available information about the laboratory (e.g., whether the laboratory is accredited under the International Organization for Standardization Standard 17025 (ISO 17025) and whether the analysis was performed in accordance with that accreditation) to determine whether the Agency can confidently rely on the laboratory's results.

4. Was the sample or specimen analyzed in accordance with documented analytical methodology that has a sensitivity and specificity that are determined by FSIS to be equivalent to the FSIS laboratory methodology in question?

B. If the Agency finds that the answers to the four questions listed are "yes," FSIS would consider that there is an appropriate basis to rely on the results of the analysis by the third party laboratory. Thus, FSIS would be prepared to take action (e.g., request a recall or institute a regulatory action) on the basis of the results obtained by the third party laboratory.

C. If the Agency finds that the answer to number 1 or number 2 is "no" or "inconclusive," then the sample result is disregarded. If the answer to number 1 and number 2 is "yes," then FSIS considers the laboratory's results in the following manner:

1. If the answer to number 3 is "yes" and the answer to number 4 is "no," then FSIS will take a verification sample;

2. If the answer to number 3 is "no" and the answer to number 4 is "no" then FSIS will disregard the sample results; and,

3. If the answer to number 3 is "no" and the answer to number 4 is "yes" then FSIS will take a verification sample.

When taking verification samples, FSIS will make an effort, whenever possible, to collect an intact sample of the same exact product and lot code(s) from the same location at which the third party sample was collected.

NOTE: Even without reliable laboratory results, FSIS may decide on the basis of the available epidemiological and other evidence that there is reason to find that product is adulterated and, thus, to act against that product.



Assistant Administrator
Office of Policy, Program and Employee Development

Decision Tree on Third Party Laboratory

Results

